

104<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 1579

To require providers of home infusion therapy services to be licensed and to limit physician referrals for home infusion therapy services in which the physician has a financial interest.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 9, 1995

Mr. BROWN of Ohio introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To require providers of home infusion therapy services to be licensed and to limit physician referrals for home infusion therapy services in which the physician has a financial interest.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Sarah Weber Home  
5       Infusion Consumer Protection Act of 1995”.

1 **SEC. 2. LICENSING OF PROVIDERS OF HOME INFUSION**  
2 **THERAPY SERVICES.**

3 (a) REQUIREMENT.—

4 (1) LICENSE REQUIREMENT.—No person shall  
5 provide (or arrange for the provision of) home infu-  
6 sion therapy services in a State unless the person is  
7 licensed by the State in accordance with this section  
8 to provide (or arrange for the provision of) such  
9 services.

10 (2) LICENSING PROCEDURE.—No State shall li-  
11 cense a person to provide (or arrange for the provi-  
12 sion of) home infusion therapy services unless the  
13 State finds that the person meets the standards for  
14 licensing established under this section.

15 (3) EXCEPTION.—Paragraph (1) shall not  
16 apply in the case of an individual providing home in-  
17 fusion therapy services without compensation for  
18 himself or herself or for a family or household mem-  
19 ber.

20 (b) STANDARDS.—

21 (1) IN GENERAL.—The Secretary of Health and  
22 Human Services (in this Act referred to as the “Sec-  
23 retary”) shall establish standards for the licensing of  
24 persons providing (or arranging for the provision of)  
25 home infusion therapy services consistent with this  
26 subsection.

1           (2) SUPERVISION.—A person licensed under  
2           this section shall only provide (or arrange for the  
3           provision of) home infusion therapy services to an  
4           individual who is under the care of a physician and  
5           under a plan established and periodically reviewed  
6           by a physician.

7           (3) PROVIDER QUALIFICATIONS.—A person  
8           shall not be licensed consistent with this section un-  
9           less the person—

10                   (A) has been determined to be capable of  
11                   providing, or arranging for the provision of,  
12                   home infusion therapy services;

13                   (B) maintains clinical records on all indi-  
14                   viduals for whom the person provides (or ar-  
15                   ranges for the provision of) such services;

16                   (C) adheres to written protocols and poli-  
17                   cies with respect to the provision (or arrange-  
18                   ment for the provision) of services;

19                   (D) makes services available (as needed) 7  
20                   days a week on a 24-hour basis;

21                   (E) coordinates all home infusion therapy  
22                   services with the patient's physician;

23                   (F) conducts a quality assessment and as-  
24                   surance program, including drug regimen re-  
25                   view and coordination of patient care;

1 (G) assures that only trained (or licensed  
2 if necessary) personnel provide infusion prod-  
3 ucts (and any other service for which training  
4 is required to safely provide the service);

5 (H) assumes responsibility for the quality  
6 of services provided by others under arrange-  
7 ments with such person;

8 (I) establishes appropriate protocols and  
9 explains such protocols clearly to patients be-  
10 fore the initiation of a treatment plan;

11 (J) is certified to be a home health agency  
12 for purposes of title XVIII of the Social Secu-  
13 rity Act or meets the requirements to be so cer-  
14 tified; and

15 (K) meets such other requirements as the  
16 Secretary may determine are necessary (i) to  
17 assure the safe and effective provision of home  
18 infusion therapy services, and (ii) respecting the  
19 quality of the provision of such services and the  
20 charges for such services.

21 A protocol referred to in subparagraph (I) shall in-  
22 clude a provision for appropriate notification of indi-  
23 viduals receiving home infusion therapy services in  
24 the event of the cancellation of the provision of those  
25 services.

1 (c) ENFORCEMENT.—

2 (1) PROVIDERS.—Any person who provides (or  
3 arranges for the provision of) home infusion therapy  
4 services in violation of subsection (a)(1) is subject to  
5 a civil money penalty (in an amount specified by the  
6 Secretary, but not to exceed \$10,000) for each such  
7 violation. The Secretary may file an action to enjoin  
8 persons from violating subsection (a)(1).

9 (2) STATES.—The Secretary shall establish a  
10 process for determining whether or not a State is  
11 complying with the requirement of subsection (a)(2).  
12 Before determining that a State has not established  
13 a licensing system that complies with such require-  
14 ment, the Secretary shall provide the State with no-  
15 tice and opportunity to respond and correct any defi-  
16 ciencies identified by the Secretary.

17 (d) AUTHORIZATION OF APPROPRIATIONS; STATE  
18 GRANTS; LICENSING FEES.—

19 (1) AUTHORIZATION OF APPROPRIATIONS.—  
20 There are authorized to be appropriated to the Sec-  
21 retary such amounts as may be necessary for the  
22 Secretary to carry out this section.

23 (2) STARTUP GRANTS.—The Secretary is au-  
24 thorized to make grants to States in order to enable

1       those States initially to establish the licensing sys-  
2       tem required under subsection (a)(2).

3           (3) LICENSING FEES.—Nothing in this Act  
4       shall be construed as preventing a State from requir-  
5       ing payment of a fee from a provider as a condition  
6       of licensing under subsection (a)(1) in order to reim-  
7       burse the State for the costs of operating the licens-  
8       ing system provided under subsection (a)(2).

9       **SEC. 3. LIMITATION ON PHYSICIAN REFERRALS.**

10       (a) GENERAL RULE.—Except as provided in this sec-  
11      tion, if a physician (or an immediate family member of  
12      such physician) has a financial relationship with an entity  
13      described in section 1877(a)(2) of the Social Security Act,  
14      then the physician may not make a referral to the entity  
15      for the furnishing of home infusion therapy services.

16       (b) INCORPORATION OF MEDICARE PHYSICIAN OWN-  
17      ERSHIP AND REFERRAL PROVISIONS.—The provisions of  
18      subsections (b) through (h) of section 1877 of the Social  
19      Security Act (other than subsections (f) and (g)(1)) shall  
20      apply with respect to subsection (a) of this section in the  
21      same manner as they apply to section 1877(a) of such Act.  
22      In applying the previous sentence, any reference to a “des-  
23      ignated health service” is deemed to be a reference to  
24      home infusion therapy services.

1 (c) TREATMENT OF PRESCRIPTION AS A REFER-  
2 RAL.—In applying subsection (b) and in addition to sec-  
3 tion 1877(h)(5) of the Social Security Act, the prescrip-  
4 tion of a drug to be administered through home infusion  
5 constitutes a “referral” by a “referring physician”.

6 **SEC. 4. HOME INFUSION THERAPY SERVICES DEFINED.**

7 For purposes of this Act, the term “home infusion  
8 therapy services” means the nursing, pharmacy, and relat-  
9 ed services, including medical supplies, intravenous fluids,  
10 delivery, and equipment, required for the provision of  
11 therapeutic agents to patients by parenteral administra-  
12 tion, including intravenous, intra-arterial, subcutaneous,  
13 epidural, intrathecal, intramuscular, and peritoneal infu-  
14 sion, by an enteral feeding tube for the purpose of improv-  
15 ing or maintaining an individual’s health condition in the  
16 individual’s residence.

17 **SEC. 5. STUDY OF MEDICARE IN-HOME COVERAGE OF CER-**  
18 **TAIN INFUSION THERAPY SERVICES.**

19 (a) IN GENERAL.—The Secretary shall conduct a  
20 study of the feasibility and economic impact of covering  
21 under part B of title XVIII of the Social Security Act on  
22 an in-home basis those infusion therapy services that  
23 would otherwise be covered under part A of such title.

24 (b) REPORT.—The Secretary shall submit to Con-  
25 gress, by not later than one year after the date of the

1 enactment of this Act, a report on the study conducted  
2 under subsection (a). Such report shall include such rec-  
3 ommendations respecting coverage of home infusion ther-  
4 apy services under part B of title XVIII of the Social Se-  
5 curity Act as the Secretary deems appropriate.

6 **SEC. 6. EFFECTIVE DATES.**

7 (a) LICENSING REQUIREMENT.—

8 (1) IN GENERAL.—Except as provided in para-  
9 graph (2), section 2(a) shall apply to home infusion  
10 therapy services provided on or after the first day of  
11 the first month that begins more than 90 days after  
12 the date of the enactment of this Act, without re-  
13 gard to whether or not the Secretary Services issues  
14 final regulations to carry out such section by such  
15 date.

16 (2) EXCEPTION WHERE STATE LEGISLATION  
17 REQUIRED.—In the case of a State which the Sec-  
18 retary determines requires State legislation (other  
19 than legislation appropriating funds) in order for the  
20 State to provide for the licensing required under sec-  
21 tion 2(a)(2), section 2(a) shall not apply in the State  
22 for home infusion therapy services provided before  
23 the first day of the first calendar quarter beginning  
24 after the close of the first regular session of the  
25 State legislature that begins after the date of the en-



1        actment of this Act. For purposes of the previous  
2        sentence, in the case of a State that has a 2-year  
3        legislative session, each year of such session shall be  
4        deemed to be a separate regular session of the State  
5        legislature.

6        (b) LIMITATION ON REFERRALS.—Section 3 shall  
7        apply to referrals made after December 31, 1995.

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